Atttorney Docket No. 21486-032 DIV2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT :	Wands et al.		
SERIAL NUMBER :	09/903,216	EXAMINER :	K. Canella
FILING DATE :	July 11, 2001	ART UNIT :	1642
FOR :	DIAGNOSIS AND TREATMENT OF MALIGNANT NEOPLASMS		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF JACK R. WANDS UNDER 37 C.F.R §1.132

I, Jack R. Wands, of East Greenwich, Rhode Island, declare and state as follows:

1. I am a co-inventor of the invention claimed in the above-referenced application and am employed by the named assignee, Rhode Island Hospital, Providence, Rhode Island.

2. I received a M.D. degree from the University of Washington in 1969 and currently serve as Chief of the Division of Gastroenterology at Lifespan Rhode Island Academic Medical Center, Director of the Liver Research Center, Professor of Medicine at Brown University School of Medicine, and Head of the Gastroenterology Section at Brown University. I am a member of the editorial boards of the academic journals Hepatology, International Hepatology Communications, Journal of Viral Hepatitis, and Viral Hepatitis Reviews, and serve as an editorial consultant for the Journal of Clinical Investigation, New England Journal of Medicine, Proceedings of the National Academy of Sciences, Journal of Infectious Disease, Gastroenterology, Journal of Virology, Virology and Nature Medicine. I have been involved in research relating to cancer for over 20 years.

3. Monoclonal antibodies specific for human aspartyl (asparaginyl) _-hydroxylase (HAAH) described and claimed in the above-referenced patent application were generated using FOCUS hepatocellular carcinoma cells as an immunogen. Monoclonal antibody 5C7 (produced by hybridoma HA15C7A; ATCC accession no. 3383), monoclonal antibody 86A (produced by hybridoma HA386A; ATCC accession no. 3385), and monoclonal antibody 19B (produced by hybridoma HA219B; ATCC accession no. 3384) were found to recognize an epitope of HAAH expressed on the surface of malignant cells. The antibodies were tested for binding to whole live cells and to formalin-fixed, paraffin-embedded tissue sections. Specificity was confirmed by data showing binding of the monoclonal antibodies to a soluble HAAH peptide containing the extracellular domain and lacking both the intracellular domain and transmembrane domain of the protein.

4. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by a fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date 3/16/04

Jack R. Wands

tradocs.1896762

Attorney Docket No. 21486-032DIV2

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FOR: Diagnosis and Treatment of Malignant Neoplasms

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STATEMENT OF JACK R. WANDS REGARDING BIOLOGICAL CULTURE DEPOSIT

I, Jack R. Wands, of East Greenwhich, Rhode Island, declare and state as follows:

1. I am a co-inventor of the invention claimed in the above-referenced application and am employed by the named assignee, Rhode Island Hospital, Providence, Rhode Island.

2. The following hybridoma cells lines were deposited on May 17, 2001, with the American Type Culture Collection (ATCC) of 10801 University Boulevard, Manassas, Va. 20110-2209 USA, an official depository for biological materials in accordance with the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure:

hybridoma FB501 (which produces monoclonal antibody FB50; ATCC accession no. PTA 3386)
hybridoma HA386A (which produces monoclonal antibody 86A; ATCC accession no. 3385)
hybridoma HA15C7A (which produces monoclonal antibody 5C7; ATCC accession no. 3383)
hybridoma HA219B (which produces monoclonal antibody 19B; ATCC accession no. 3384)

3. The hybridoma cell lines were deposited after the filing date of patent application U.S. Serial Number 09/436,184 (from which the present divisional application claims priority) and are the same hybridoma cells lines as described in the above-referenced patent application and in my possession at the time the application was filed.

4. The hybridoma cell lines were tested by the ATCC and were confirmed to be viable on May 30, 2001 (ATCC filing receipt and viability statement, dated June 27, 2001, which is of record, having been submitted to the Patent Office on July 15, 2003).

5. In the event that the deposited hybridoma cell liens mutate, become nonviable, or be inadvertently destroyed, Applicant will replace the cell lines for at least 30 years from the date of the original deposit, or at least 5 years from the date of the most recent request for release of a sample or for the life of any patent issued on the above-referenced patent application, whichever is longer.

6. The deposit of cell lines was made under conditions of assurance of (a) ready accessibility thereto by the public if a patent is granted whereby all restrictions tp the availability to the public of the cell lines so deposited will be irrevocably removed upon the granting of the patent , and (b) access to the culture will be available during pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. § 1.14 and 35 U.S.C. § 122.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by a fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date 3/16/04

Jack R. Wands